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23599 7590 07/29/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
SHITERENGARTS, SAMANTHA L				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/535,246

**Applicant(s)**

DORSCH ET AL.

**Examiner**

Samantha L. Shterengarts

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) 1-17 (in part), 18, 19-22 (in part), 23, and 24 (in part) is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19-22, and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 18 May 2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. The instant application is a national stage entry of PCT/EP03/12080 filed October 30, 2003, which claims foreign priority benefit to German Patent No. 102 54 336.4, filed November 21, 2002. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
- 2.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on May 18, 2005 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. This IDS document was considered. A signed copy of form 1449 is enclosed herewith.

### ***Election/Restrictions***

3. In a telephone conversation with Applicant's representative, Csaba Henter, on July 14, 2008, Examiner noted that the restriction requirement contained an inadvertent error. All instances of "thienyl" should actually read "thiophene."
4. Applicant's election with traverse of Group I, Claims 1-17, 19-22, and 24 (in part) drawn to products of the formula (I) wherein D is thiophene which is unsubstituted or mono- or polysubstituted; X is C=O, Y is Ar-diyl; and T is piperdin-1-yl which is substituted or unsubstituted, in the reply filed on May 8, 2008 is acknowledged. The traversal is on the ground(s) that the patent office has not established that it would pose an undue burden to examine the full scope of the claimed invention.

Search burden is not a criterion for unity in a lack of unity requirement and therefore, this traverse does not address Examiner's arguments made for the lack of unity of invention.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a)

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Groups I – XI lack unity of invention since under 37 CFR 1.475: the technical feature, in this case, the non-variable core of the instantly claimed compounds is C(=O)-NH. This core technical feature is not a special technical feature because it fails to define a contribution over the prior art as can be seen, for example, in WO 02/057236, which discloses the same non-variable core on page 40, example 4.

Therefore, Groups I-XI are not so linked as to form a single general inventive concept and there is a lack of unity of invention because they lack a special technical feature as the

technical feature present fails to define a contribution over the prior art. The core technical feature that is being claimed is taught by the prior art. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

The requirement is still deemed proper and is therefore made FINAL.

4. As per MPEP 803.02, the Examiner will determine whether the entire scope of the claims is patentable. The elected invention, Group I, was found free of the art. The search was expanded to compounds wherein T is the full scope of T in generic claim 1. As discussed with Applicant's representative on July 16, 2008, the elected invention, Group I, will be: Claims 1-17, 19-22, and 24 (in part) drawn to products of the formula (I) wherein D is thiophene which is substituted or mono- or polysubstituted; X is C=O, Y is Ar-diyl; and T is a mono- or bicyclic saturated, unsaturated or aromatic carbo- or heterocycle having 0 to 4 N, O and/or S atoms which is mono- or disubstituted by =O, =S, =NR<sup>2</sup>, =N-CN, =N-NO<sub>2</sub>, =NOR<sup>2</sup>, =NCOR<sup>2</sup>, =NCOOR<sup>2</sup>, =NOCOR<sup>2</sup> and may furthermore be mono-, di- or trisubstituted by R<sup>2</sup>, Hal, A, -[C(R<sup>3</sup>)<sub>2</sub>]<sub>n</sub>-Ar, -[C(R<sup>3</sup>)<sub>2</sub>]<sub>n</sub>-Het, -[C(R<sup>3</sup>)<sub>2</sub>]<sub>n</sub>-cycloalkyl, OR<sup>2</sup>, N(R<sup>2</sup>)<sub>2</sub>, NO<sub>2</sub>, CN, COOR<sup>2</sup>, CON(R<sup>2</sup>)<sub>2</sub>, NR<sup>2</sup>COA, NR<sup>2</sup>CON(R<sup>2</sup>)<sub>2</sub>, NR<sup>2</sup>SO<sub>2</sub>A, COR<sup>2</sup>, SO<sub>2</sub>NR<sup>2</sup> and/or S(O)<sub>n</sub>A. Since the elected Group (including the expansion of variable T) was found free of the art, but the entire scope of the claims was not found to be allowable (see section 7 below), claims to all other nonelected claims and nonelected subject matter will be held withdrawn from further consideration.

### ***Status of Claims***

5. Claims 1-24 are currently pending in the instant application. Claims 18 and 23 are withdrawn for being drawn to a nonelected invention. Claims 1-17, 19-22, and 24 (in part) are objected to for containing nonelected subject matter; however, the elected subject matter contained therein has been examined on its merits.

### ***Specification***

6. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(c) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
  - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
  - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and

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preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(c).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.



***Claim Rejections - 35 USC § 112***

***(First Paragraph)***

7. Claims 1-17, 19-22, and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutically acceptable salts and stereoisomers of the formula (I), does not reasonably provide enablement for pharmaceutically acceptable solvates thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

***The Nature of the Invention***

The nature of the invention is compounds of the Formula (I) and their pharmaceutically acceptable salts, derivatives, solvates, and stereoisomers thereof, including mixtures thereof in all ratios.

***The State of the Prior Art and the Predictability or lack thereof in the art***

Active pharmaceutical ingredients are frequently delivered to the patient in the solid-state as part of an approved dosage form (e.g., tablets, capsules, etc.). Solids provide a convenient, compact, and generally stable format to store an active pharmaceutical ingredient or a drug product. Understanding and controlling the solid-state chemistry of active pharmaceutical ingredients, both as pure drug substances and in formulated products, is therefore an important aspect of the drug development process. Active pharmaceutical ingredients can exist in a variety of distinct solid forms, including polymorphs, solvates, hydrates, salts, co-crystals, and amorphous solids. Each form displays unique physicochemical properties that can profoundly influence the bioavailability, manufacturability purification, stability, and other performance

characteristics of the drug. Hence, it is critical to understand the relationship between the particular solid form of a compound and its functional properties.

For ionizable compounds, preparation of salt forms using pharmaceutically acceptable acids and bases is a common strategy to improve bioavailability. However, the preparation of other solid forms such as polymorphs, solvates, and hydrates, are not so common to be predictable. In order to obtain patent protection on these forms, some of which may have significantly different properties and relevance as development candidates, it is essential to prepare them, identify conditions for making them, and evaluate their properties as valuable new pharmaceutical materials. A large number of factors can influence crystal nucleation and growth during this process, including the composition of the crystallization medium and the processes used to generate super-saturation and promote crystallization (Morissette et al. *Advanced Drug Delivery Reviews* 2004, 56, 275-300). Therefore, for these reasons, the state of the prior art is one of unpredictability.

As stated above, crystalline solids can exist in the form of polymorph, solvates or hydrates. "Phase transitions such as polymorph interconversion, desolvation of solvate, formation of hydrate, and conversion of crystalline to amorphous form may occur during various pharmaceutical processes, which may alter the dissolution rate and transport characteristics of the drug. Hence, it is desirable to choose the most suitable and stable form of the drug in the initial stages of drug development" (Vippagunta et al., abstract, Vippagunta, Sudha R. "Crystalline Solids." *Advanced Drug Delivery Reviews* 48(2001): 3-26.) In further discussing the predictability of the formation of solvates, Vippagunta et al. discloses that "predicting the formation of solvates or hydrates of a compound and the number of molecules of water or

solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compounds" (page 18, section 3.4).

*The Amount of Direction or Guidance Present and Presence or Absence of Working Examples*

The specification ¶[0069] contains the following disclosure regarding solvates. "The term solvates of the compounds is taken to mean adductions of inert solvent molecules onto the compounds which form owing to their mutual attractive force. Solvates are, for example, mono- or dihydrates or alcoholates." This disclosure does not define solvates in any way, or limit these terms in a way to enable one to make and use solvates of each embodiment of the instantly claimed compounds of formula (I). Also, dihydrates and alcoholates are examples, rather than definitions of the "solvates" being claimed. There is no data present in the specification for the preparation of solvates of compounds of the Formula (1). It is not discussed which specific compounds can exist in these forms. Finally, there are no working examples present in the disclosure for the preparation of solvates.

*The Breadth of the Claims*

The instant breadth of the rejected claims is broader than the disclosure, specifically; the instant claims include any solvates of the claimed compounds.

*The Quantity of Experimentation Needed and the Level of Skill in the Art*

While the level of skill in the pharmaceutical arts is high, it would require undue experimentation for one of ordinary skill in the pertinent art to prepare *any* solvate of the compounds of Formula (I). The science of crystallization has evolved such that, without guidance or working examples in the specification, the claims lack enablement.

8. Claims 1-17, 19-22, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite the limitation, "derivatives thereof" in reference to the instantly claimed compounds and their "derivatives." Applicant has not described the claimed genus of "derivatives" in a manner that would indicate they were in possession of the full scope of this genus, or even to describe what this genus is comprised of. The instant specification ¶ [0070], discloses that, "The term pharmaceutically usable derivatives is taken to mean, for example, the salts of the compounds according to the invention and so-called prodrug compounds." This exemplification is not a definition that allows Examiner to ascertain that Applicant was in possession of the full scope of this genus. Additionally, if this were to be acceptable definition, which it is not, the current state of the art in terms of pro-drugs is unknown and also not described in the instant specification.

"Pro-drugs" are commonly known in the art as drugs which are administered in an inactive (or less active) form, and then metabolized in vivo into an active metabolite. As disclosed in Stella (Expert Opinions Prodrugs as therapeutics), "prodrugs are bioreversible derivatives of drug molecules used to overcome some barriers to the utility of the parent drug molecule. These barriers include, but are not limited to, solubility, permeability, stability, presystemic metabolism, and targeting limitations" (277). Stella, Valentino J, Expert Opinion of

Therapeutic Patents, *Prodrugs as therapeutics*, 2004 14(3): 277-280. Wolff et al. (Burger's Medicinal Chemistry, 5<sup>th</sup> Ed., Vol. 1, pgs. 975-977, 1994) summarizes that state of the prodrug art, the lengthy research involved in successfully identifying a prodrug, and difficulties of extrapolating between species. With the limited direction and exemplification the specification offers, it is highly unpredictable that the compounds of the Formula (I) will actually form effective prodrugs. Testa, Bernard, Biochemical Pharmacology, *Prodrug Research: futile or fertile?* 68 (2004) 2097-2106, discloses, on page 2098, the various challenges in prodrug research, concluding that all of these challenges may render prodrug optimization difficult to predict and achieve. Finally, Ettmayer, Peter, Medicinal Chemistry, *Lessons Learned from Marketed and Investigational Prodrugs*, 47(10) (2004) 2394-2404, discloses, on page 2401, that "the prodrug strategy should only be considered as a last resort to improve the oral bioavailability of important therapeutic agents" and "At the beginning of each prodrug program, there should be a clear definition of the problem to solve and defect to improve. The prodrug approach should not be misunderstood as a universal solution to all barriers to a drug's usefulness, and on page 2402, "The majority of all prodrug approaches face the challenge of identifying the optimal prodrug plus its activation system to enhance or prolong the concentration of the active principle at the site of action. Because of the complex situation of prodrug transport and processing, we recommend, especially for novel prodrug principles, that the first step should be to design and investigate different prodrug prototypes of high diversity (different attachment sites, linkers, promoieties, hydrolytic, oxidative, reductive activation, chemical vs. enzymatic activation)." Ettmayer et al. concludes that "the focus on victorious prodrugs should not be misunderstood as neglecting the inherent difficulties and additional layers

of complexity a prodrug strategy might face." The evidence supports the conclusion that the method of making claimed prodrugs is a subject for further study and experimentation.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plain for obtaining the claimed chemical invention." Eli Lilly, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

In the instant case, the claimed "derivatives thereof" encompass any compound that contains the identical core as the instantly claimed compound, with a differing of substituents quoted for the identical purpose. Applicants describe no "derivatives thereof" or pro-

drugs. Applicants have not described this genus in a manner that would allow one skilled in the art to immediately envisage the compounds contemplated for use. As such, the claims lack adequate written description for the claimed "derivatives thereof."

***(Second Paragraph)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-17, 19-22, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite the phrase, "pharmaceutically usable derivatives." It is unclear what Applicant is seeking patent protection for, and what the definition of "usable" and "derivatives" is in this instance. Instant claims 22 and 24 also recite the phrase, "at least one further medicament active ingredient." It is unclear what Applicant means by "one further medicament." Proper clarification of these terms is required.

***Conclusion***

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/  
Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626